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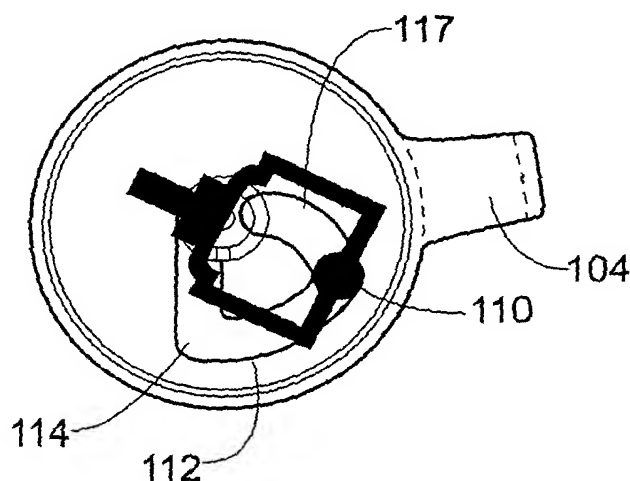
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(54) Title: DELIVERY DEVICE



(57) Abstract: There is described a medicament delivery device comprising a metering member adapted to dispense a measured amount of medicament, an actuator (3), a medicament delivery passage and a delivery passage cover (4) adapted to move from a closed to an open position, characterised in that the device includes means to prevent activation of the actuator (3) until the cover (4) is moved to the open position, said actuator (3) being capable of subsequent multiple activations without moving the cover (4) back to the closed position. There is also described a method of treatment which comprises the use of such a device.



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## Delivery Device

This invention relates to a novel medicament delivery device, for example, an inhalation device, and to a novel means of delivering medicaments.

5

US Patent No. 4,834,083 describes a pressurised aerosol inhaler which is provided with a catch means for prevention of unintended depression of the actuator and means for opening and closing the mouthpiece which is operably linked to the catch means.

10

European Patent No 428 380 describes a pressurised aerosol inhaler which is provided with a protective casing which comprises a removable mouthpiece cover which is linked to means for cocking the inhaler.

15 Dry powder inhalers are known, such as TECHNOHALER, being developed by Innovata Biomed in the UK. Such a device is described in International Patent Application No WO 93/16748 (PCT/GB93/00335). WO '748 describes an inhaler which comprises a disc shaped cartridge having a plurality of medicament carrying receptacles around the periphery of the cartridge. Each receptacle comprises a spool  
20 housed in a spool carrier. Each spool has a flange at each end which forms a tight slidable fit within the body of the spool carrier. The space left between the body of the spool and the spool carrier is filled with an appropriate medicament.

Protective covers are also known to be used in connection with dry powder inhalers.

25 The Accuhaler™ comprises a disc shaped inhaler provided with a peripheral mouthpiece and peripheral actuator. A protective cover is provided which is rotatable about a central spigot, from a closed position to an open position wherein the actuator and mouthpiece are both exposed. However, one disadvantage with the Accuhaler protector is that the actuator and mouthpiece are exposed sequentially.  
30 One disadvantage of the Accuhaler device is that when the mouthpiece cover is rotated and the mouthpiece exposed, the actuator is primed ready for a single activation. However if multiple actuations are desirable this can only be achieved by

closing the mouthpiece cover and then reopening it. Such a process adds complexity to the operations required to use the device; is time consuming and may present particular difficulties to the elderly or those with arthritic joints.

- 5 The Jago dry powder inhaler, which is being developed by Skyepharma AG, comprises a system which can be loaded and activated by only a single movement of the mouthpiece cover. However, in order to cock the inhaler the hinged mouthpiece is pull downwards and once the medicament is inhaled, in order to re-cock the inhaler the mouthpiece must be replaced and subsequently removed. Thus in order  
10 to achieve multiple doses of medicament the mouthpiece cover must be repeatedly closed and opened.

- We have now surprisingly found a novel means for use with a medicament delivery device, e.g. an inhalation device and, in particular, a dry powder inhaler, which  
15 prevents activation of an actuator until a protective cover is removed, but which also permits multiple actuations of the device.

- Thus, according to the invention we provide a medicament delivery device comprising a metering member adapted to dispense a measured amount of  
20 medicament, an actuator, a medicament delivery passage and a delivery passage cover adapted to move from a closed to an open position, characterised in that the device includes means to prevent activation of the actuator until the cover is moved to the fully open position, said actuator being capable of subsequent multiple activations without moving the cover back to the closed position.

- 25 The delivery device of the invention may comprise a single metering member; however, the device may optionally comprise a plurality of metering members.

- In one embodiment of the invention the means to prevent activation of the actuator  
30 may comprise a locking mechanism. Such a locking mechanism may comprise an actuator lever adapted to engage with a plunger, said plunger being adapted to act upon a metering member, when the cover is in the closed position the locking

mechanism acts to lock the plunger, and when the cover is in the open position the plunger is unlocked.

5 In a particularly preferred embodiment the actuator requires the plunger to act in a radial direction thus the locking mechanism is such that in the locked position it acts to prevent radial movement of the plunger whilst in the open position radial movement is permitted. Such a device which comprises means for radial expression of medicament is described in our co-pending application No. 9920839.9.

10 The cover may be rotatably mounted and may be operably linked to a rotatably mounted plunger locking plate, such that rotation of the cover from a closed position rotates the locking plate from a locked to an unlocked position.

15 In an especially preferred embodiment the locking plate comprises a channel adapted to co-operate with at least a portion of the plunger, said channel comprising an arcuate circumferential portion provided with a closed end, the other end opening to a radial portion. Thus in the locked position the plunger is positioned at the closed end of the circumferential channel and radial movement of the plunger is prevented. Upon rotation of the locking plate the plunger is positioned at the open end of the  
20 circumferential channel, the actuator lever may now be operated so as to cause radial movement of the plunger and thus actuation of the metering member. The channel may comprise a groove in the locking plate but is preferentially partially or wholly an aperture.

25 In an especially preferred embodiment of the invention the plunger is provided with a spigot, preferentially at one end of the plunger, i.e. distal to the portion which acts upon the medicament metering member, the spigot being perpendicular to the operation of the plunger and positioned so as to engage with the actuator and the locking plate. The spigot may engage directly with the actuator or it may engage  
30 with an actuator plate which may be separate to or integral with the actuator. The actuator plate may be provided with a groove or an aperture and the plunger, e.g. the spigot, may rests against the wall of the groove or aperture, such that activation of

the actuator causes the actuator plate to rotate. The actuator plate groove or aperture is also caused to rotate and the wall of the groove or aperture pushes against the spigot to cause radial movement.

- 5 In a further embodiment of the invention a guide plate may be provided to guide the plunger. The guide plate may optionally be positioned between actuator plate and the plunger. The guide plate may be provided with means for guiding the radial movement of the spigot and/or the plunger. Therefore, preferentially, the guide means may comprise a radial aperture through which the spigot projects. The  
10 dimensions of the guide aperture being such that the spigot forms a snug fit between the aperture walls.

In an especially preferred embodiment of the invention the medicament delivery device may be an inhaler, for example, a dry powder inhaler (DPI).

- 15 Thus, according to a further aspect of the invention we provide an inhalation device comprising a metering member adapted to dispense a measured amount of medicament, an actuator, an inhalation passage, a mouthpiece and a mouthpiece cover adapted to move from a closed to an open position characterised in that the  
20 device includes means to prevent activation of the actuator until the cover is moved to an open position, said actuator being capable of multiple activations without moving the cover back to the closed position.

- A further disadvantage of the Accuhaler device is that it is possible to only partially  
25 rotate the cover to an intermediate position so that the actuator is exposed whilst the mouthpiece is not. This intermediate position can enable the actuator to be depressed and medicament ejected even though the mouthpiece is not exposed. This can lead to inadvertent depression of the actuator or, for example, in the case of children who may not want to take medication, deliberate actuation whilst avoiding inhalation. A  
30 further embodiment of the present invention also overcomes this additional disadvantage.

Therefore in a particular embodiment of the present invention the means to prevent activation of the actuator may comprise a delivery passage cover which is also an integral actuator cover, the cover being adapted to move from a closed position in which the delivery passage and actuator are both covered to an open position wherein the delivery passage and actuator are exposed simultaneously.

As with the first embodiment, the delivery device is preferentially an inhaler, for example, a dry powder inhaler.

Thus, according to a further aspect of the invention we provide an inhalation device comprising a metering member adapted to dispense a measured amount of medicament, an actuator, an inhalation passage, a mouthpiece and a mouthpiece cover wherein the mouthpiece cover also forms an integral actuator cover, the integral actuator cover being adapted to move from a closed position in which the mouthpiece and actuator are both covered to an open position wherein the mouthpiece and actuator are exposed characterised in that the mouthpiece and actuator are exposed simultaneously.

The inhalation device of the invention may comprise any conventionally known inhaler. However, it is preferred that the inhaler is a dry powder inhaler (DPI). The integral mouthpiece and actuator cover may be used on any conventionally known DPIs, however, a preferred DPI is that known as TECHNOHALER.

Thus, the inhaler is preferentially a flat or disc shaped inhaler. The actuator may be positioned on the periphery of a disc shaped inhaler. In one embodiment of the invention both the actuator and the mouthpiece are situated on the circumferential or peripheral edge of the inhaler. In that case the integral cover will comprise a first and second limb, the first limb comprising a mouthpiece cover and the second limb comprising an actuator cover. An aperture is provided between the first and second limbs and a second aperture is provided adjacent at least on of the first or second limbs, distal to the other limb. Thus upon rotation of the integral cover from the

closed position to the open position the first aperture overlies the mouthpiece and the second aperture overlies the actuator.

5 In a preferred embodiment, the actuator is positioned in one of the flat surfaces of the disc shaped inhaler.

A variety of actuator types may be used in the inhaler of the invention, but preferably the actuator is provided in the form of a push button. An inhaler of the TECHNOHALER type is provided with one or more spools containing medicament  
10 to be dispensed. Preferentially, the inhaler comprises a cartridge provided with a plurality of medicament chambers, each provided with a spool and a pre-set amount of medicament. In such a case the actuator may simply provide a push rod which is attached to push button which is provided with biasing means, eg a spring.

15 Thus in a disc shaped inhaler, the integral mouthpiece and actuator cover is rotatable from a closed position in which the mouthpiece and actuator are both covered, to an open position in which the mouthpiece and actuator are both exposed. The cover may therefore be rotatable about a central spigot which may be situated on one or both sides of the inhaler.

20 Thus, the cover may comprise a plastics strip wherein a first end comprises a mouthpiece cover and a second end comprises an actuator cover. The second end may simply be provided with an aperture such that when the cover is rotated from the closed position to the open position, the aperture overlies the actuator enabling  
25 the actuator to be depressed. In an especially preferred embodiment the second end of the cover is provided with a floating push button. In the closed position the push button abuts the outer surface of the casing of the inhalation device. In the open position the floating push button overlies the actuator and may therefore be depressed enabling the actuator to operate.

30 In an especially preferred embodiment the cover comprises a third portion which is distal to the first portion. The third portion is adapted to facilitate gripping and

rotation of the cover by a patient. Therefore the gripping portion may be positioned on the opposite side to the axis of rotation of the first portion or, alternatively, the third portion may be offset at an angle against the first portion. Therefore, when the cover comprises a plastics strip comprising two angled portions, when the cover is  
5 rotated to the open position the mouthpiece is preferentially exposed by the area between the two angled portions.

According to a further feature of the invention we also provide a dry powder inhaler comprising a plurality of metering members adapted to dispense a measured amount  
10 of medicament and held on a substantially circular cartridge, an inhalation passage and a mouthpiece, and a push button which engages a push rod adapted to move one of the plurality of metering members from a medicament retaining position to a medicament dispensing position characterised in that the mouthpiece and push button are provided with an integral cover.

15 The cover may comprise any material conventionally used in inhalation devices. Thus, preferably the cover comprises a plastics material. If the inhalation device also comprises a plastics material, the cover and the inhalation device may comprise the same or different material.

20 A variety of medicaments may be administered by using the medicament delivery device of the invention, such medicaments would be well known to one skilled in the art. When the medicament delivery device comprises an inhaler, then such suitable medicaments would generally include antibiotics, bronchodilators or other anti-  
25 asthma drugs. Such medicaments include, but are not limited to bronchodilators, e.g. fenoterol, formoterol, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol and terbutaline; non-selective beta-stimulants such as isoprenaline; xanthine bronchodilators, e.g. theophylline, aminophylline and choline theophyllinate; anticholinergics, e.g. ipratropium bromide; mast cell stabilisers, e.g. sodium cromoglycate and ketotifen; bronchial anti-inflammatory agents, e.g. nedocromil  
30 sodium; and steroids, e.g. beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations thereof.



Specific combinations of medicaments which may be mentioned include combinations of steroids, such as, beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations of to bronchodilators, such as, 5 formoterol and salmeterol. It is also within the scope of this invention to include combinations of one or more of the aforementioned steroids with one or more of the aforementioned bronchodilator. A specific combination which is preferred is a combination of fluticasone and salmeterol.

10 Further medicaments which may be mentioned include systemically active materials, such as, proteinaceous compounds and/or macromolecules, for example, hormones and mediators, such as insulin, human growth hormone, leuprolide and alpha interferon; growth factors, anticoagulants, immunomodulators, cytokines and nucleic acids.

15

According to a further feature of the invention we provide a method of administering a medicament to a patient using a delivery system as hereinbefore described.

We further provide a method of treatment of a patient suffering from a disorder 20 which comprises the administration of a therapeutically effective amount of an appropriate medicament using an inhaler system as hereinbefore described.

Thus, we also provide a method of treatment of a patient suffering from a bronchial disorder which comprises the administration of a therapeutically effective amount of 25 an appropriate medicament using an inhaler system as hereinbefore described.

In a yet further alternative we provide a method of treatment of a patient suffering from insulin dependant diabetes which comprises the administration of a therapeutically effective amount of insulin using an inhaler system as hereinbefore 30 described.

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a plan view of an inhaler of the second invention in the closed position;

5 Figure 2 is a plan view of an inhaler in the open position;

Figure 3 is a cross-sectional view of an inhaler of the invention; and

Figure 4 is a partially cut away plan view of an inhaler in the closed position;  
10

Figure 5 is a perspective view of an inhaler of the first embodiment of the invention;

Figure 6 a-c is a plan view of a plunger, a locking disc and an actuator disc respectively;  
15

Figure 7 is a perspective view of an inhaler in the locked position;

Figure 8 is a schematic representation of the locking mechanism in the locked position;  
20

Figure 9 is a perspective view of an inhaler in the unlocked position;

Figure 10 is a schematic representation of the locking mechanism in the unlocked position;  
25

Figure 11 is a perspective view of an inhaler in the actuated position;

Figure 12 is a schematic representation of the locking mechanism in the actuated position;  
30

Figure 13 is a perspective view of an inhaler in the reset position;

Figure 14 is a schematic representation of the locking mechanism in the reset position;

Figure 15 is a perspective view of an inhaler returned to the rest position; and

5

Figure 16 is a schematic representation of the locking mechanism returned to the rest position.

Referring to Figures 1 and 2, an inhaler (1) is provided with a mouthpiece (2) and an actuator (3). A cover (4) is adapted in the closed position to cover the mouthpiece (2) and the actuator (3). The cover (4) is also provided with a floating push button (5) which, when in the closed position, is remote from the actuator (3).

Referring to Figure 3, the cover (4) is rotatable about a central spigot (6) (not shown in Figures 1 and 2) to an open position in which the mouthpiece (2) is exposed and the floating push button (5) overlies the actuator (3).

Referring to Figure 4, the actuator system comprises a push rod (7) connected to an actuator (3). The actuator (3) is biased away from the push rod (7) by means of a spring (8). The actuator (3) is held in position by a circumferential shoulder (9) in the body (10) of the inhaler (1).

The cover (4) is provided with a floating push button (5) which is held in position by the surface of body (10) of the inhaler (1) or the actuator (3) and a circumferential shoulder (11) in the cover (4).

In use, in the closed position the cover (4) overlies the mouthpiece (2) and the actuator (3). The cover (4) is rotated about a central spigot to the open position in which the mouthpiece (2) is exposed and a floating push button (5) overlies the actuator (3). A patient depresses the push button (5) which depresses the actuator (3). The push rod is then depressed into a spool carrier in cartridge (12) thus dispensing medicament into the inhaler.

Referring to Figures 5, an inhaler (101) comprises a body (102), a mouthpiece cover (103) and an actuator (104).

- 5 Referring to Figures 6 a-c, a locking mechanism comprises a plunger (105), a locking plate (106) and an actuator plate (107). The plunger (105) comprises a push rod (108) adapted to engage a medicament metering member (not shown). At the distal end (109) from the push rod (108), the plunger (105) is provided with a spigot (110). The locking plate (106) comprises a thin rotatable disc and is provided with  
10 an aperture (111) in the form of a channel comprising an arcuate circumferential portion (112) with a closed end (114). The open end (113) opens into a radial portion (115).

- The actuator plate (107) comprises a thin disc provided with a peripheral lever  
15 (116) and an aperture (117) in the form of an arcuate radial channel. The actuator plate (107) is also provided with a circumferential rim (118) which enables the locking plate (106) to sit in position on the actuator plate (107).

- In use the actuator plate (107) rests upon the plunger (105) and the spigot (110)  
20 protrudes through the aperture (117). The locking plate (106) sits inside the rim (118) of the actuator plate (107) and the closed end (113) of the locking plate aperture (111) overlies the actuator plate aperture (117). The spigot (110) also protrudes through the locking plate aperture (111) at the point of overlap.

- 25 Referring to Figures 7 and 8, with the actuator (104) in the rest position and the mouthpiece cover (103) closed, the spigot (110) protrudes through the apertures (111 and 117). Radial movement of the spigot (110) is prevented by the wall (118) of the arcuate circumferential portion (112) of the locking disc aperture (111). The mouthpiece cover (103) is operably linked to the locking plate (106) via a central  
30 point (119).

Referring to Figures 9 and 10, the mouthpiece cover (103) is rotated to expose the mouthpiece (120). This also causes the locking plate (106) to rotate so that the spigot (110) is altered from the closed end (113) of the locking plate aperture (111) to the open end (114).

5

Referring to Figures 11 and 12, the actuator lever (104) is rotated to activate the inhaler. The outer wall (121) of the arcuate aperture (117) acts against the spigot (110) causing radial movement of the spigot (110) and the plunger (105). Optionally, an intermediate plate (not shown) may be positioned between the actuator plate (107) and the plunger (105). Such an intermediate plate may be provided with a radial aperture which may assist in guiding the spigot (110) when it undergoes radial travel.

10

Referring to Figures 13 and 14, the actuator lever (104) may be returned to the rest position without the locking mechanism reactivating. Thus, the spigot (110) returns to the open end (114) of the arcuate circumferential portion (112) of the aperture (111) in the locking plate (106). The process of activation of the actuator may be repeated as often as possible.

15

Referring to Figures 15 and 16, when the mouthpiece cover is closed, the locking plate (106) rotates to return the spigot (110) to the closed end (113) of the aperture, deactivating the actuator.

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**CLAIMS**

1. A medicament delivery device comprising a metering member adapted to dispense a measured amount of medicament, an actuator, a medicament delivery  
5 passage and a delivery passage cover adapted to move from a closed to an open position, characterised in that the device includes means to prevent activation of the actuator until the cover is moved to the open position, said actuator being capable of subsequent multiple activations without moving the cover back to the closed position.
- 10 2. A medicament delivery device according to claim 1 characterised in that the means to prevent activation of the actuator comprises a locking mechanism.
3. A medicament delivery device according to claim 2 characterised in that the  
15 locking mechanism comprises an actuator lever adapted to engage with a plunger, said plunger being adapted to act upon the metering member such that when the cover is in the closed position the locking mechanism acts to lock the plunger, and when the cover is in the open position the plunger is unlocked.
- 20 4. A medicament delivery device according to claim 2 characterised in that the locking mechanism is adapted when in the closed position to prevent radial movement of the plunger whilst in the open position radial movement is permitted.
5. A medicament delivery device according to claim 3 characterised in that the  
25 cover may be rotatably mounted and may be operably linked to a rotatably mounted plunger locking plate, such that rotation of the cover from a closed position rotates the locking plate from a locked to an unlocked position.
6. A medicament delivery device according to claim 5 characterised in that the  
30 locking plate comprises a channel adapted to co-operate with at least a portion of the plunger, said channel comprising an arcuate circumferential portion provided with a closed end, the other end opening to a radial portion.

7. A medicament delivery device according to claim 5 characterised in that in the locked position the plunger is positioned at the closed end of the circumferential channel and radial movement of the plunger is prevented.
- 5 8. A medicament delivery device according to claim 5 characterised in that upon rotation of the locking plate the plunger is positioned at the open end of the circumferential channel.
- 10 9. A medicament delivery device according to claim 3 characterised in that the plunger is provided with a spigot at one end of the plunger.
10. A medicament delivery device according to claim 3 characterised in that the spigot engages with an actuator plate which may be separate to or integral with the
- 15 actuator.
11. A medicament delivery device according to claim 10 characterised in that the actuator plate is provided with an aperture and the spigot rests against the wall of the aperture.
- 20 12. A medicament delivery device according to claim 1 characterised in that a guide plate is provided to guide the plunger.
13. A medicament delivery device according to claim 1 characterised in that the
- 25 guide plate is positioned between actuator plate and the plunger.
14. A medicament delivery device according to claim 1 characterised in that the guide means comprises a radial aperture through which the spigot projects.
- 30 15. A medicament delivery device according to claim 1 characterised in that the medicament delivery device is an inhaler.

16. A medicament delivery device according to claim 15 characterised in that the inhaler is a dry powder inhaler (DPI).

5 17. A medicament delivery device according to claim 1 characterised in that the means to prevent activation of the actuator may comprise a delivery passage cover which is also an integral actuator cover, the cover being adapted to move from a closed position in which the delivery passage and actuator are both covered to an open position wherein the delivery passage and actuator are exposed simultaneously.

10 18. A medicament delivery device according to claim 17 characterised in that the delivery device is an inhaler

15 19. A medicament delivery device according to claim 18 characterised in that the device comprises a metering member adapted to dispense a measured amount of medicament, an actuator, an inhalation passage, a mouthpiece and a mouthpiece cover adapted to move from a closed to an open position characterised in that the device includes means to prevent activation of the actuator until the cover is moved to an open position, said actuator being capable of multiple activations without moving the cover back to the closed position.

20 20. An inhalation device comprising a metering member adapted to dispense a measured amount of medicament, an actuator, an inhalation passage, a mouthpiece and a mouthpiece cover wherein the mouthpiece cover also forms an integral actuator cover, the integral actuator cover being adapted to move from a closed position in which the mouthpiece and actuator are both covered to an open position wherein the mouthpiece and actuator are exposed characterised in that the mouthpiece and actuator are exposed simultaneously.

25 21. An inhalation device according to claim 20 characterised in that the device is a dry powder inhaler (DPI).



22. An inhalation device according to claim 20 characterised in that the device is a flat or disc shaped inhaler.
23. An inhalation device according to claim 15 characterised in that the actuator  
5 is positioned on the periphery of the inhaler.
24. An inhalation device according to claim 21 characterised in that the actuator and the mouthpiece are both situated on the periphery of the inhaler.
- 10 25. An inhalation delivery device according to claim 20 characterised in that the integral cover comprises a first and second limb, the first limb comprising a mouthpiece cover and the second limb comprising an actuator cover, an aperture being provided between the first and second limbs and a second aperture being provided adjacent at least one of the first or second limbs, distal to the other limb,  
15 such that upon rotation of the integral cover from the closed position to the open position the first aperture overlies the mouthpiece and the second aperture overlies the actuator.
26. An inhalation device according to claim 20 characterised in that the actuator  
20 is positioned in one of the flat surfaces of the inhaler.
27. An inhalation device according to either of claims 16 or 20 characterised in that the device is a TECHNOHALER<sup>TM</sup>.
- 25 28. An inhalation device according to claim 20 characterised in that the actuator is provided in the form of a push button.
29. An inhalation device according to claim 28 characterised in that the actuator comprises a push rod attached to a push button provided with biasing means.  
30
30. An inhalation device according to claim 29 characterised in that the biasing means is a spring.

31. An inhalation device according to claim 1 characterised in that the integral cover is rotatable about a central point.
- 5 32. A dry powder inhaler comprising a plurality of metering members adapted to dispense a measured amount of medicament and held on a substantially circular cartridge, an inhalation passage and a mouthpiece, and a push button which engages a push rod adapted to move one of the plurality of metering members from a medicament retaining position to a medicament dispensing position characterised in  
10 that the mouthpiece and push button are provided with an integral cover.
33. An inhalation device comprising a mouthpiece, an actuator and a cover which is adapted, in a closed position to cover the mouthpiece and the actuator, the cover being provided with a floating push button which, when the cover is in the closed  
15 position is remote from the actuator.
34. A method of administering a medicament to a patient delivery system according to claim 1.
- 20 35. A method of administering a medicament to a patient which comprises the use of a medicament delivery device according to claim 15.
36. A method of treatment of a patient suffering from a disorder which comprises the administration of a therapeutically effective amount of an appropriate  
25 medicament using a medicament delivery device according to claim 15.
37. A method of treatment according to claim 36 characterised in that the disorder is a bronchial disorder.
- 30 38. A method of treatment according to claim 36 characterised in that the disorder is insulin dependant diabetes and the medicament is insulin.

39. A medicament delivery device or an inhalation device substantially as described with reference to the accompanying description and drawings.

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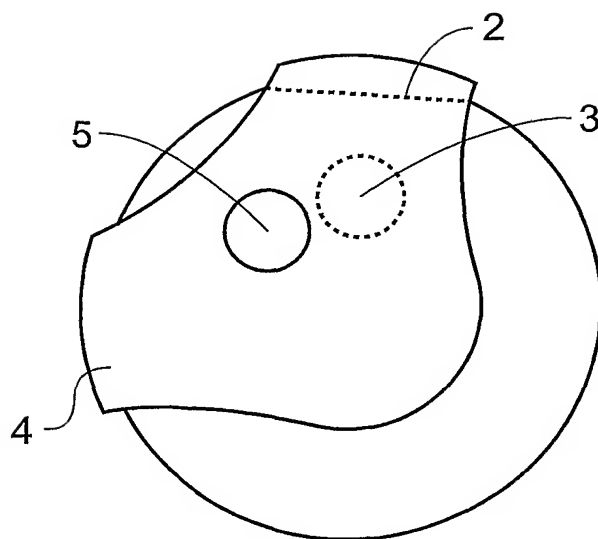


Fig. 1

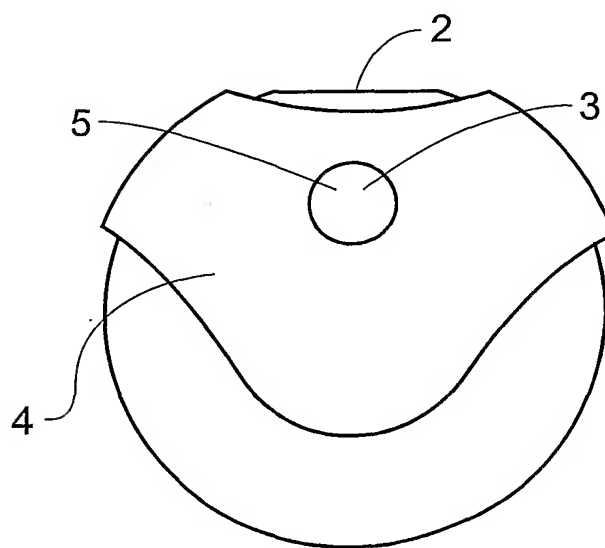


Fig. 2

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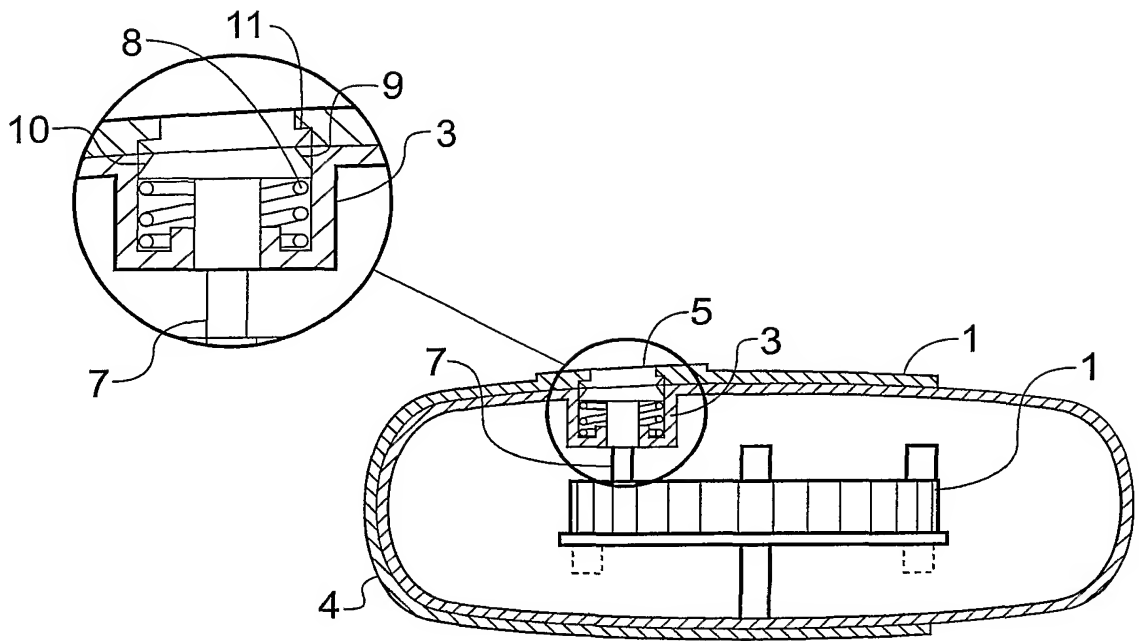


Fig. 3

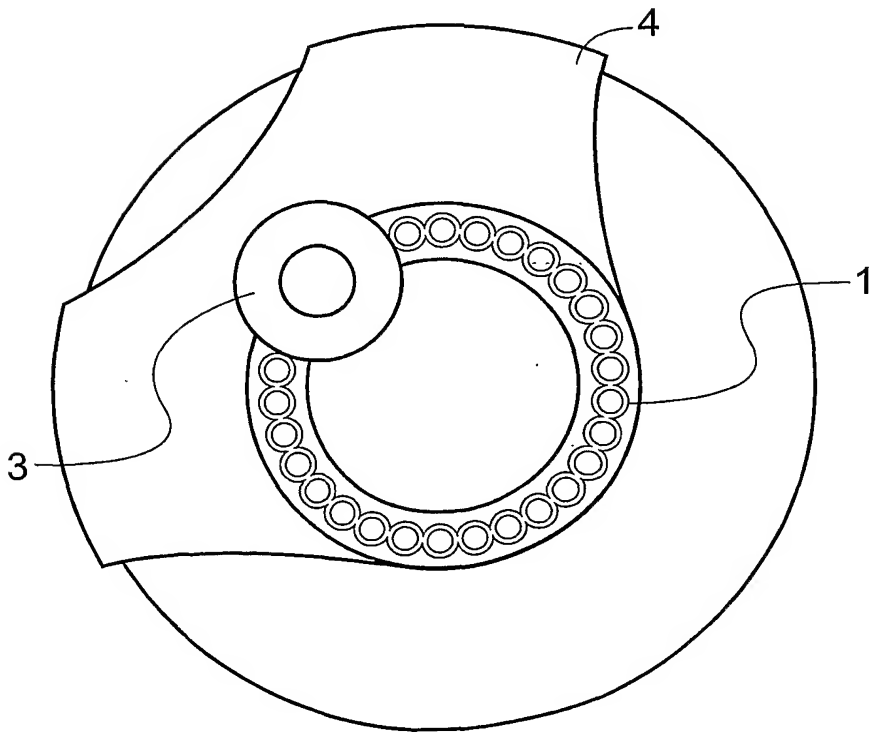


Fig. 4

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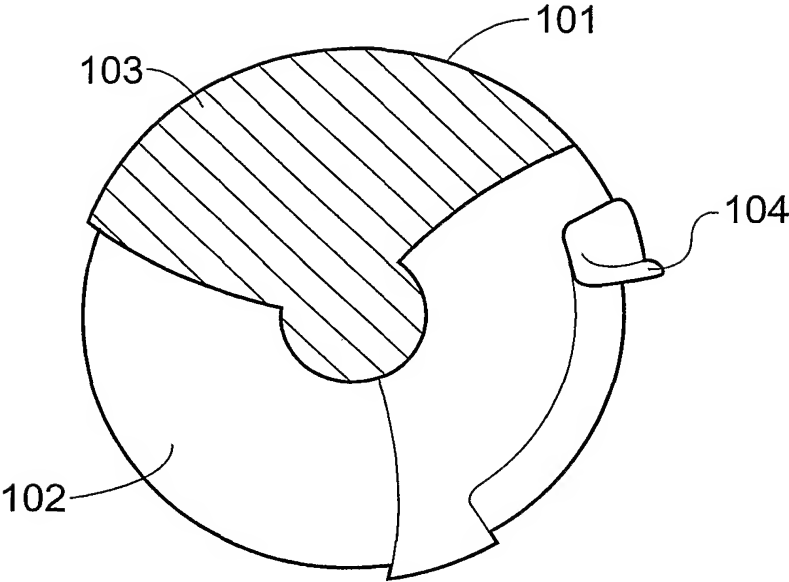


Fig. 5

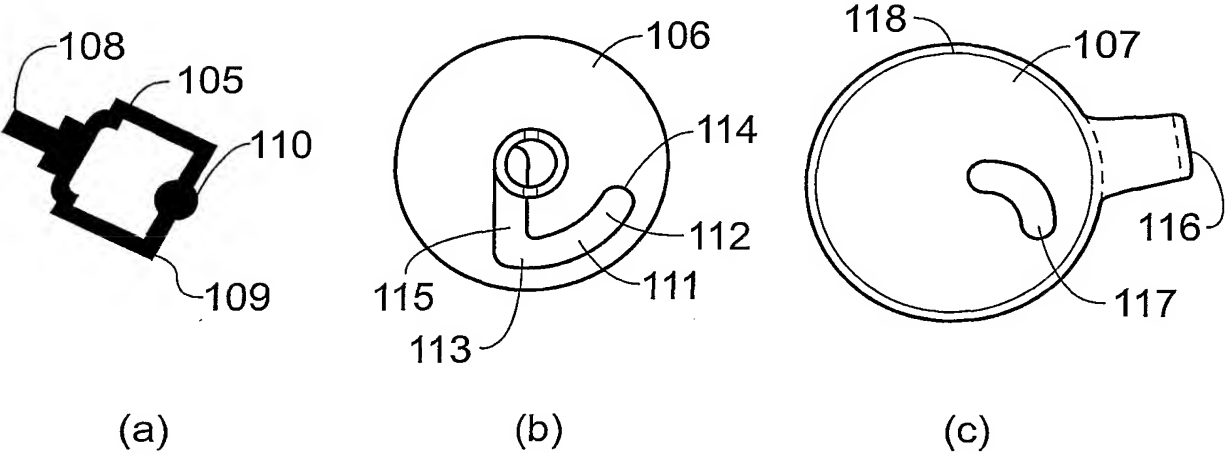


Fig. 6

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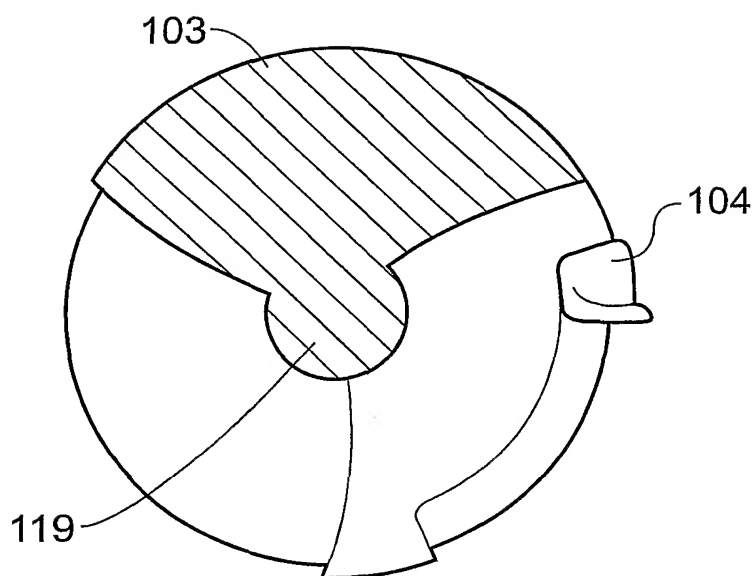


Fig. 7

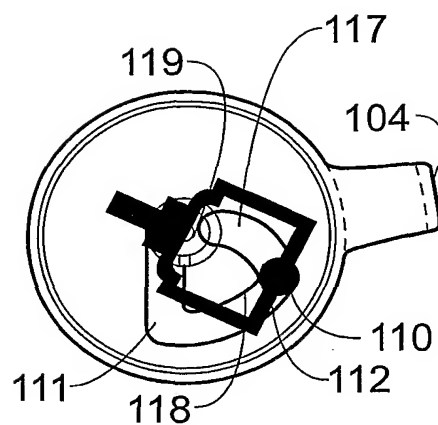


Fig. 8

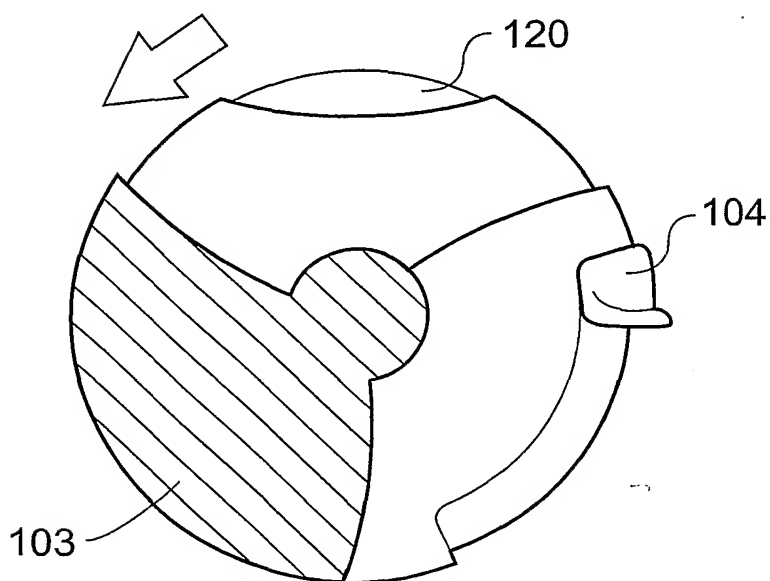


Fig. 9

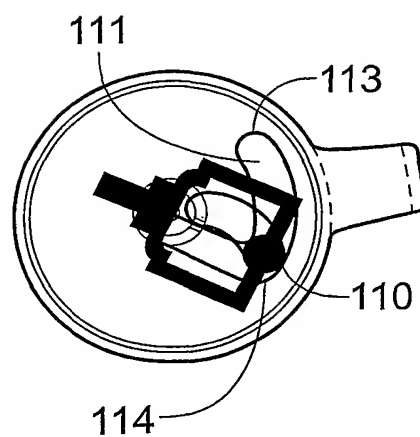


Fig. 10

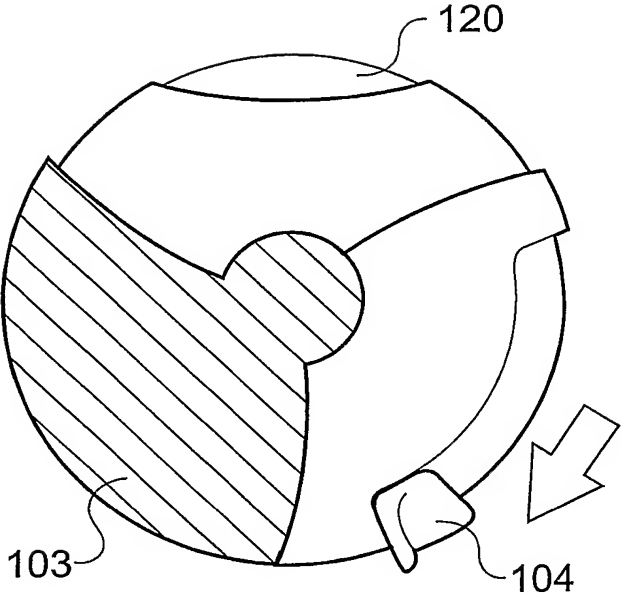


Fig. 11

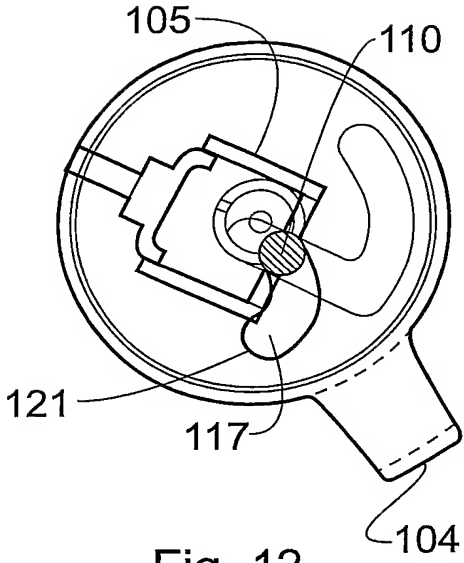


Fig. 12

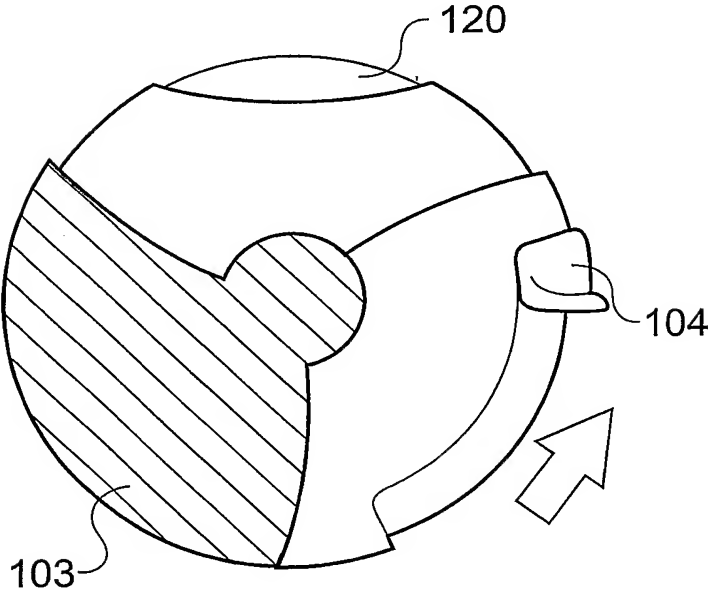


Fig. 13

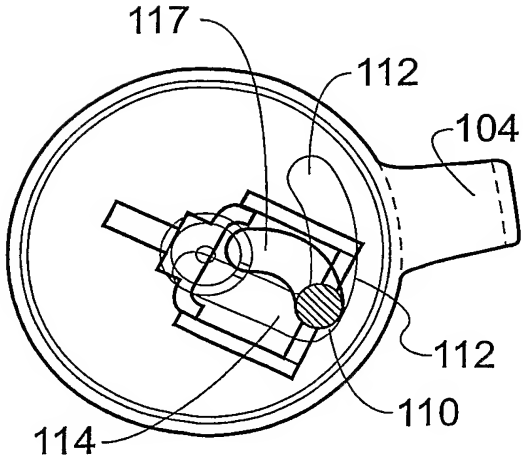


Fig. 14



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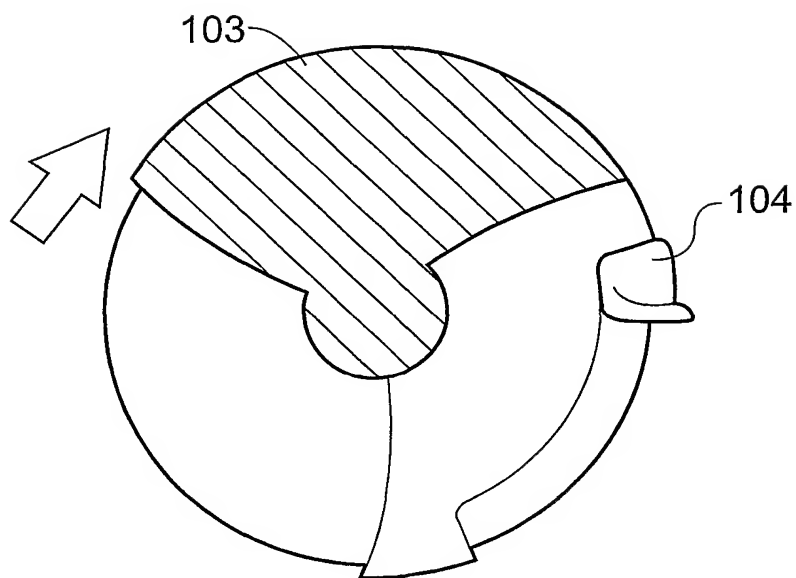


Fig.15

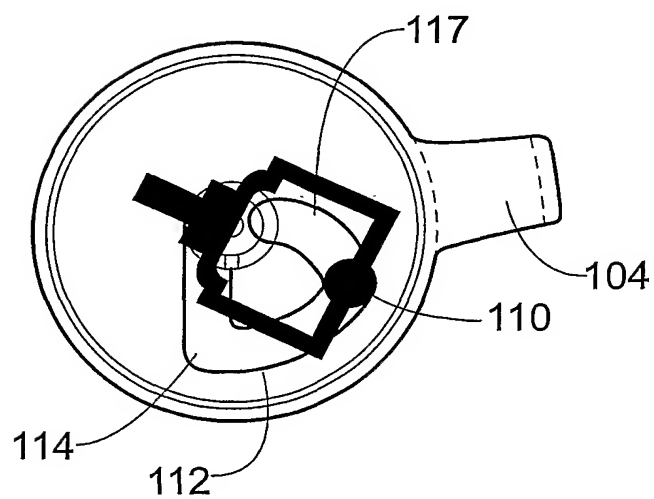


Fig. 16

# INTERNATIONAL SEARCH REPORT

Intern Application No

PCT/GB 01/02854

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M B65D A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 065 472 A (ANDERSON GREGOR JOHN MCLENNAN ET AL) 23 May 2000 (2000-05-23) column 5, line 25 - line 65; figures ---	1,2, 15-24,26
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☒ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

15 October 2001

Date of mailing of the international search report

24/10/2001

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## INTERNATIONAL SEARCH REPORT

Intern	Application No
PCT/GB	01/02854

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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International Application No. PCT/GB 01 02854

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 27,39

see Rules 6.2a and 6.3a PCT

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

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